From the
INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

PCT

WRITTEN OPINION
(PCT Rule 66)

To:

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Date of mailing *(day/month/year)*	03.08.2004
Applicant's or agent's file reference: P1243 PCT	**REPLY DUE** **within 3 month(s)** from the above date of mailing

International application No.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/US 03/33525	21.10.2003	22.10.2002

International Patent Classification (IPC) or both national classification and IPC
A61F2/06

Applicant
MEDTRONIC VASCULAR, INC.

1. This written opinion is the **first** drawn up by this International Preliminary Examining Authority.

2. This opinion contains indications relating to the following items:

I	☒	Basis of the opinion
II	☐	Priority
III	☐	Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
IV	☐	Lack of unity of invention
V	☒	Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
VI	☐	Certain documents cited
VII	☐	Certain defects in the international application
VIII	☐	Certain observations on the international application

3. The applicant is hereby **invited to reply** to this opinion.

When? See the time limit indicated above. The applicant may, before the expiration of that time limit, request this Authority to grant an extension, see Rule 66.2(d).

How? By submitting a written reply, accompanied, where appropriate, by amendments, according to Rule 66.3. For the form and the language of the amendments, see Rules 66.8 and 66.9.

Also: For an additional opportunity to submit amendments, see Rule 66.4.
For the examiner's obligation to consider amendments and/or arguments, see Rule 66.4 bis.
For an informal communication with the examiner, see Rule 66.6.

If no reply is filed, the international preliminary examination report will be established on the basis of this opinion.

4. The final date by which the international preliminary examination report must be established according to Rule 69.2 is: 22.02.2005

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I. Basis of the opinion

1. With regard to the **elements** of the international application *(Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this opinion as "originally filed")*:

Description, Pages

1-13 as originally filed

Claims, Numbers

1-20 as originally filed

Drawings, Sheets

1/8-8/8 as originally filed

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

   These elements were available or furnished to this Authority in the following language: , which is:

   ☐ the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)).
   ☐ the language of publication of the international application (under Rule 48.3(b)).
   ☐ the language of a translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

   ☐ contained in the international application in written form.
   ☐ filed together with the international application in computer readable form.
   ☐ furnished subsequently to this Authority in written form.
   ☐ furnished subsequently to this Authority in computer readable form.
   ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
   ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. The amendments have resulted in the cancellation of:

   ☐ the description, pages:
   ☐ the claims, Nos.:
   ☐ the drawings, sheets:

5. ☐ This opinion has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)).

6. Additional observations, if necessary:

V. Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims	1,4,14,17,18,20
Inventive step (IS)	Claims	2,3,5-8,15
Industrial applicability (IA)	Claims	

2. Citations and explanations

see separate sheet

Re Item V

Reasoned statement with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

Reference is made to the following documents:

D3: US5788979 (ECKHARD ALT; AXEL STEMBERGER (D)) 4 AUGUST 1998 (1998-08-04)

D4: US6228845 (Maura Donovan, Paul M. Stein (US)) 8 May 2001 (2001-05-08)

which were not cited in the search report. A copy of the documents is appended hereto.

1. The subject-matter of claims 1,4,14,17,18,20 cannot be considered new (Article 33(2) PCT) for the following reasons:

With relation to claims 1 and 4, document D3 which is regarded as being the closest prior art to the subject-matter of claim 1, discloses (the references in parentheses applying to related documents) a stent coated with a material that can be a biodegradable polymer which is used as a drug carrier (column 4, lines 24-27). To the drug carrier can be added, for example, a thrombus inhibitor (column 3, lines 31-38) that is a therapeutic agent as claimed in claim 4. Several other ingredients can be added to the drug carrier as disclosed in the examples 1 to 6. In general, it is well known in the art to provide a stent on a form of a cylindrical wire and coat it with material suitable for releasing a drug as the prior art disclosed in D3.
D3 also discloses the different use of the coating material when applied to the inner or to the outer sides of an open cylindrical structure of a stent with consequences on the process of applying the coating. Namely, the coating applied to the outer surface would face the vessel and would be intended to inhibit restenosis while the coat applied to the inner surface would be intended to prevent thrombus formations (see column 6 lines 9-13, column 10 lines 4-19) resulting in big differences in the coating characteristics on both sides of the stent; these characteristics would be such as the thickness of each coating (see column 5 lines 28-34, column 13, lines 1-4) or the coated applied material. These differences are such, that it is disclosed the possibility of separately coating the two sides of the stent (column 10, lines 15-19) resulting in an "eccentric coating" around the stent's wire as claimed in claim 1 of the application. That is, the "eccentric coating" or different thicknesses of inside and outside sides applied coatings can be a consequence of separately coating the two sides of the stent with different materials for different purposes.

With relation to independent claim 14, the drug carrier disclosed in D3 is a

solution of a polymer (for example, poly-D L-lactid) and a solvent (chloroform) (see column 7, lines 50-54). In the disclosed several examples, to the carrier solution can be added selective ingredients as an anti-coagulant herapin or an anti-thrombotic as urokinase.

The step of applying the coating in an eccentric way was already above exhaustively discussed, namely, the differences in thicknesses that the layers from the inside and the outside sides of the stent can present .

The curing step is defined as the drying step where the solvent evaporates after which the coating material becomes a thin adhesive layer on the stent (see column 8, lines 39-54).

With relation to claims 17,20 as mentioned above (see column 10, lines 12,13), the coating is applied by spraying.

With relation to claim 18, D3 particularly calls the attention to carefully dry the final layer before the stent is implanted (see column 12, lines 58-67).

2. The present application does not meet the criteria of Article 33(1) PCT, because the subject-matter of claims 2,3,5-8,15 does not involve an inventive step in the sense of Article 33(3) PCT.

With relation to claim 2,3 one would easily conclude that one of the sides of the stent would be thicker than the other according to the intended purposes as claimed in claims 2 and 3.

With relation to claim 5, it is not clear from D3 that the number of layers of the proposed multi-layer embodiment would be two and that the second or last layer, would be a cap coating regulating elution of a therapeutic agent disposed in the adjacent layer. However, document D4, in one embodiment, discloses a stent with a second polymer coating with greater sustained release capabilities (see column 14, lines 34-49), that is, to control or regulate release of a substance placed in the adjacent first polymer coating. It would therefore be obvious for the person skilled in the art to provide the stent disclosed in D3 separately coated on it's outside and inside surfaces, each with one layer of coating material and apply over the whole stent a second layer of material with for the same purposes as the second coating described in D4.

With relation to claims 6,7,8 different layers with the same or different beneficial agents, can be coated to the stent of D3 (see column 5, line 58 - column 6, line 8). These are considered to have uniform thicknesses (see again column 13, lines 1-4). It would therefore be obvious to apply only two layers of coating to the stent with the second containing a therapeutic agent.

With relation to claim 15, to spray the coating material over the outside side of the

stent, it is well known in the art to fix the stent to a mandrel as disclosed in D4 (see column 15, lines 5-8).

3. The following deficiencies were found in the application:

3.1 Contrary to the requirements of Rule 5.1(a)(ii) PCT, the relevant background art disclosed in the document D3 is not mentioned in the description, nor is this document identified therein.

3.2 In order to meet the requirements of Rule 6.3(b) PCT, independent claims should be properly cast in the two-part form, with those features which in combination are part of the prior art being placed in the preamble (Rule 6.3(b)(I)PCT) and with the remaining features being included in the characterising part (Rule 6.3(b)(ii)PCT. If, however, the Applicant is of the opinion that the two part form would be inappropriate, then reasons therefor should be provided in the letter of reply. In addition, the Applicant should ensure that it is clear from the description which features of the subject matter of claim 1 are already known in combination from document D3.

3.3 The features of the claims are not provided with reference signs placed in parentheses (Rule 6.2(b) PCT).

3.4 The vague and imprecise statement in the description on paragraph 0045 implies that the subject-matter for which protection is sought may be different to that defined by the claims, thereby resulting in lack of clarity (Article 6 PCT) when used to interpret them.